

CLAIMS

1. Apparatus for facilitating placement of a cardiac pacing lead within the vascular system of a patient comprising:
 - (a) an elongated guidewire of a first predetermined flexibility and
5 having a predetermined outer diameter and length;
 - (b) an elongated, polymeric lead body whose flexibility is less than the predetermined flexibility of the guidewire, the lead body having a proximal end, a distal end and a lumen extending therebetween, said lumen sized to receive the guidewire therethrough and with an electrode disposed on the lead body proximate the
10 distal end thereof; and
 - (c) means on the guidewire adapted to cooperate with a predetermined portion of the lead body when the proximal end of the guidewire is pushed in a distal direction for positioning the electrode at a desired location in the vascular system, the flexibility of the guidewire relative to the lead body maintaining
15 the electrode at the desired location as the guidewire is extracted from the lumen.
2. The apparatus of claim 1 wherein the guidewire comprises:
 - a. a floppy distal zone having a spiral winding;
 - b. a contiguous zone joined to said floppy distal zone, the largest cross-sectional diameter of said contiguous zone being no larger than the largest cross-
20 sectional diameter of said floppy distal zone and exhibiting said first predetermined flexibility.
3. The apparatus of claim 2 wherein said contiguous zone is made of a material which makes said contiguous zone stiffer than said floppy distal zone.
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4. The apparatus of claim 2 wherein said contiguous zone comprises a solid wire.
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5. The apparatus of claim 4 wherein said solid wire has a circular cross-section.

6. The apparatus of claim 1 wherein at least a portion of said guidewire has a lubricious outer surface.

7. The apparatus of claim 6 wherein said lubricious outer surface is a
5 hydrophilic coating.

8. The apparatus of claim 6 wherein said lubricious outer surface comprises a polytetrafluoroethylene coating.

10 9. The apparatus of claim 6 wherein said lubricious outer surface comprises a silicone film coating.

10. For implantation and placement of at least one cardiac electrode, an apparatus comprising:

15 (a) a cardiac lead having said electrode disposed thereon, the lead having a lumen defined by a wall and a transition defining a shoulder projecting inwardly from said wall;

(b) a guidewire adapted to fit through said lumen and comprising:

(1) a floppy distal zone with a spiral winding;

20 (2) a contiguous proximal zone joined to said floppy distal zone, said proximal zone comprising a solid wire having a shoulder dimensioned to engage the shoulder projecting inwardly from the lumen wall of the cardiac lead when said guidewire is inserted into said lumen, said proximal zone being stiffer than the floppy distal zone.

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11. The apparatus of claim 10 and further including an intermediate zone, comprises a spiral wound wire.

30 12. The apparatus of claim 10 and further including an intermediate zone between the proximal zone and the distal zone which comprises a solid wire having a circular cross-section.

13. The apparatus of claim 10 further comprising means for temporarily locking said guidewire to said lead.

14. For implantation and placement of at least one cardiac electrode, an apparatus comprising:

(a) a cardiac lead having said electrode disposed thereon and having an interior wall defining a lumen;

(b) a guidewire comprising:

(i) a floppy distal zone comprising a spiral winding surrounding a ribbon core member, and a spherical tip covering one end of the ribbon core member and the spiral winding;

(ii) an intermediate zone joined to said floppy distal zone; and

(15) (iii) a proximal zone joined to said intermediate zone, said proximal zone being stiffer than both the floppy distal zone and the intermediate zone.

(c) means for transmitting forces between said cardiac lead and said guidewire.

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15. The apparatus of claim 13 wherein said means for transmitting forces between said cardiac lead and said guidewire includes a shoulder formed between the proximal zone and intermediate zone of the guidewire for engaging a member projecting from the interior wall of the lumen of the cardiac lead.

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16. For use in combination with a guide catheter to implant a cardiac lead, said cardiac lead having at least one electrode, a central lumen defined by a helically wound wire coil turned in a first direction, a guidewire comprising:

(a) a distal zone comprising a spiral winding turned in a second direction opposite to the first direction and having a square cut tip;

(b) an intermediate zone joined to said distal zone, the largest cross-

sectional diameter of said intermediate zone being no larger than the largest cross-sectional diameter of said distal zone; and

5 (c) a proximal zone having a cross-sectional diameter greater than the largest cross-sectional diameter of said intermediate zone, said proximal zone being joined to said intermediate zone by a tapered shoulder and being stiffer than both the distal zone and the intermediate zone.

17. The apparatus of claim 16 wherein said guidewire has a diameter sufficiently small to be insertable into said central lumen after placement of the lead yet 10 the distal zone has a diameter sufficiently large that said tip is able engage the wire coil which defines said lumen to retain the lead in place during removal of the guide catheter.

18. In combination with a guide catheter and a cardiac stimulating lead, a 15 finishing wire for insertion in the lumen of the cardiac lead for removing said guide catheter while holding the lead in place, comprising:

20 a floppy distal zone with a distal tip,
 an intermediate zone joined to said floppy zone, the intermediate zone having a stiffness different from that of the floppy distal zone, and
 a proximal zone joined to the intermediate zone, the proximal zone being stiffer than the intermediate zone and the floppy zone wherein the finishing wire, when inserted past the distal end of the guide catheter, engages fictionally and holds the lead in place during removal of the guide catheter.

25 19. A finishing wire as in claim 18 wherein,
 the distal tip has an atraumatic spherical tip.
 e distal tip has an atraumatic tapered tip.

30 20. A finishing wire as in claim 18 and further including
 a means for temporarily locking the finishing wire to the lead during removal for the guide catheter.

21. A finishing wire as in claim 20 wherein,
the means for temporarily locking is attached to the distal end of the finishing
wire.
- 5 22. A finishing wire as in claim 18 wherein,
the means for temporarily locking is attached proximate to the proximal end of
the finishing wire.
- 10 23. A finishing wire as in claim 18 wherein,
the means for temporarily locking is attached to the finishing wire proximate
the proximal end thereof and a separate temporary locking means is disposed
proximate the distal end of the finishing wire.
- 15 24. A finishing wire as in claim 18 wherein,
the temporary locking means extends along a predetermined length of the
finishing wire.
- 20 25. A finishing wire as in claim 22 wherein,
the temporary locking means comprises a radially expandable and contractible
braided element attached to the finishing wire.
26. A finishing wire as in claim 20 wherein,
the temporary locking means comprises sutures on the finishing wire adapted
to cooperate with a terminal pin on the cardiac lead.
- 25 27. A finishing wire as in claim 16 and further including,
a means for temporarily locking the finishing wire to the lead during removal
for the guide catheter.

28. A finishing wire as in claim 27 wherein,
the means for temporarily locking is attached proximate to the distal end of the
finishing wire.

5 29. A finishing wire as in claim 27 wherein,
the means for temporarily locking is attached proximate to the proximal end of
the finishing wire.

10 30. A finishing wire as in claim 27 wherein,
the temporary locking means extends along a predetermined length of the
finishing wire.

15 31. A finishing wire as in claim 30 wherein,
the temporary locking means comprises a radially expandable and contractible
braided element attached to the finishing wire.

20 32. A finishing wire as in claim 27 wherein,
the temporary locking means comprises sutures cooperating with a terminal pin
on the lead.

25 33. A finishing wire as in claim 29 wherein,
the temporary locking means comprises a shoulder on the lead for engaging a
shoulder on the finishing wire.

34. A method for installing a pacing lead within a patient comprising the
steps of:

providing a guide catheter, a body implantable pacing lead and an elongated
finishing wire;

advancing the guide catheter through the vascular system of a patient until a
30 distal end thereof is at a predetermined location;

advancing the pacing lead through the guide catheter until an electrode on a

distal end portion of the pacing lead is positioned beyond a distal end of the guide catheter and adjacent tissue to be stimulated;

- inserting a finishing wire into a lumen of the pacing lead, the finishing wire engaging a wall defining the lumen of the lead to permit the guide catheter to be
- 5 removed from surrounding relation with the lead without the lead being moved from a desired placement;

- removing the guide catheter from the patient; and
- removing the finishing wire from the lumen of the lead while holding the proximal end of the lead so that the lead is not dislodged during removal of the
- 10 finishing wire from the patient.

35. The method of claim 34 and further comprising the step of:
temporarily locking the finishing wire to the lead at the distal end of the
finishing wire while the guide catheter is being removed.

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36. A method of removing a guide catheter from surrounding relation with respect to an over-the-wire pacing lead having an electrode thereon proximate a distal end thereof after the pacing lead has been installed in a patient with the electrode at a desired location, comprising the step of:

- 20 (a) removing a guidewire from a lumen of the over-the-wire pacing lead;
- (b) inserting a finishing wire into the lumen of the over-the-wire pacing lead, said finishing wire having a means for engaging the finishing wire with the lead;
- (c) stripping the guide catheter from the over-the-wire pacing lead and over a proximal portion of the finishing wire while holding the finishing wire
- 25 stationary; and
- (d) withdrawing the finishing wire from the patient while holding a proximal end of the pacing lead stationary so as not to displace the electrode from the desired location.

37. A method for installing a cardiac pacing lead in a patient, comprising the steps of:

- (a) providing a pacing lead having an elongated flexible tubular body with a proximal end, a distal end and a lumen extending therebetween, the lead body supporting an electrode proximate the distal end;
- (b) providing a guiding catheter having an elongated flexible tubular body with a proximal end, a distal end and a lumen extending therebetween, the lumen of the guiding catheter sized to permit passage of the pacing lead therethrough;
- (c) providing an elongated flexible guidewire having an atraumatic distal tip, the guidewire having an outer diameter of a size permitting passage thereof through the lumen of the pacing lead;
- (d) providing an elongated flexible finishing wire having an outer diameter smaller than a diameter of the lumen of the pacing lead;
- (e) percutaneously inserting the distal end of the guiding catheter into the vascular system at a predetermined location and advancing the guiding catheter along the vascular system until the distal end of the guiding catheter reaches a predetermined location;
- (f) advancing the guidewire through the lumen of the guiding catheter with the distal tip of the guidewire extending beyond the distal end of the guiding catheter to a target location where the electrode on the pacing lead is to be positioned in the patient;
- (g) threading the distal end of the pacing lead onto the proximal end of the guidewire and advancing the pacing lead over the guidewire until the electrode is at the target location;
- (h) holding the proximal end portion of the pacing lead while withdrawing the guidewire from the lumen of the pacing lead;
- (i) inserting the finishing wire at least partially within the lumen of the pacing lead;
- (j) holding the proximal end portion of the finishing wire to stabilize the pacing lead against movement while removing the guiding catheter from the patient; and

(k) removing the finishing wire from the lumen of the pacing lead and from the patient.